

Remarks

Claims 70-80 are pending in the subject application. Applicants acknowledge that claims 72-76 and 78 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have amended claims 72, 74, 76, and 79 and added new claims 81-87. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed and previously presented. Certain of the claim amendments (renumbering of dependencies) have been made to correct antecedent basis issues. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 70-87 are currently before the Examiner (with claims 70, 71, 77, 79, 80, 81 and 87 reading on the elected invention). Favorable consideration of the pending claims is respectfully requested.

Submitted herewith is a supplemental Information Disclosure Statement (IDS), accompanied by the form PTO/SB/08, and copies of the list references. Applicants request that the references in the IDS be made of record in the subject application.

The specification is objected to because of informalities in the use of trademarks and it contained embedded hyperlinks or other forms of browser executable code. Applicants respectfully submit that these issues are moot in view of the amendments made to the specification. By this Amendment, Applicants have also amended the subject specification to correct inadvertent typographical errors. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

The Examiner notes that the listing of references in the specification is not a proper form for an Information Disclosure Statement (IDS). Applicants submitted an IDS in the subject application on September 21, 2006 and a supplemental IDS on May 30, 2007 and the Examiner has acknowledged her consideration of the IDSes in the instant Action. Applicants acknowledge that only those references submitted in their IDS filed September 21, 2006 and May 30, 2007 or cited on form PTO-892 have been considered by the Examiner.

The abstract of the disclosure of the subject specification has been objected to because it is not directed to the invention. By this Amendment, Applicants have amended the abstract. Applicants respectfully submit that no new matter has been incorporated in this Abstract. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

The disclosure is objected to because of informalities. Specifically, the Examiner has indicated that the current address for ATCC is not reflected on page 23, lines 3-4 of the specification. By this Amendment, Applicants have amended the specification to reflect the current address for ATCC as provided by the Examiner. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

The Examiner has indicated that the title of the invention is not descriptive and that a new title is required that is clearly indicative of the invention to which the claims are directed. Applicants note that the title was amended to "Compositions and Methods for Regulating NK Cell Activity" in the Election and Preliminary amendment filed April 24, 2009. Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

Claims 70, 71, 77, 79 and 80 is rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. Applicants respectfully assert that the claims as filed are enabled. Submitted herewith is a declaration by the undersigned indicating that this antibody has been deposited under the terms of the Budapest Treaty and that all restrictions will be removed upon the grant of a patent in this matter. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claim 80 is rejected under 35 U.S.C. § 102(e) as anticipated by Velardi *et al.* (U.S. published Application No. 2005/0037002). The Office Action indicates that the Velardi *et al.* reference discloses making antibodies that block the KIR2DL receptors of NK cells by: (1) immunizing a non-human mammal, including a mouse, rat, bovine, porcine, horse, rabbit, goat, sheep or XENOMOUSE, with an immunogen comprising a KIR2DL polypeptide, including one on the surface of an NK cell, (2) preparing monoclonal antibodies from the said immunized animal, wherein said monoclonal antibodies bind said KIR2DL polypeptide, (3) selecting monoclonal antibodies from step (2) that cross react with at least two different serotypes of KIR2DL polypeptides, and (4) selecting monoclonal antibodies of (3) that inhibit KIR2DL-mediated inhibition of NK cells, such as KIR2DL-mediated inhibition of NK cytotoxicity, and additionally selecting and isolating an antibody that binds to a human (*i.e.*, a primate) NK cell and to KIR2DL1 and KIR2DL2/3. The Office Action also indicates that the Velardi *et al.* reference discloses that the antibodies preferably bind a common determinant of KIR2DL human receptors such as KIR2DL1

and KIR2DL2/3, and that the monoclonal antibody is DF200, binds to the same epitope as DF200 or competes for binding with DF200, and that the antibody used for therapy may have a human or non-human primate IgG1 or IgG3 Fc portion. Finally, Velardi *et al.* is cited as disclosing administering an injection of a composition comprising two compounds such as the inhibitory antibody (DF200) and IL-2 in a pharmaceutically acceptable excipient. Applicants also note that the Office Action indicates that Velardi *et al.* has a priority date of July 23, 2003 and that claim 80 finds support in Provisional Patent Application 60/545,471, filed February 14, 2004. Applicants respectfully assert that the Velardi *et al.* reference does not anticipate the claimed invention as it is not prior art to the invention of claim 80.

As noted above, Velardi *et al.* is a U.S. Patent Application Publication filed on July 23, 2004 which claims the benefit of U.S. Provisional Application 60/489,489 (filed July 24, 2003; a copy of which is provided in the Information Disclosure Statement concurrently filed with this response). The '489 priority document has been reviewed and it is respectfully submitted that there is no disclosure of a composition comprising the claimed antibody (or fragments thereof) and IL-2 within that reference. Indeed, the only mention of interleukin 2 found in the '489 priority documents is found at pages 19-24, Examples 1-2 (where a composition of PBLs was cultured in the presence of feeder cells and IL-2 to obtain a polyclonal NK cell population [Example 1] or rituximab was incubated with IL-2 and the EB6 antibody in an ADCC assay [Example 2]). As there is no mention of a composition comprising the DF200 monoclonal antibody (or fragments thereof) in combination with IL-2 in the '489 priority document, the earliest effective filing date for such a disclosure in Velardi *et al.* is the filing date of July 23, 2004. This date is after the earliest effective filing date accorded claim 80 (February 14, 2004). Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including

any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

FCE/jb/sl

Attachments: Supplemental IDS
Deposit Declaration